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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,613	08/04/2000	Holly Hogrefe	4121.0116-07	6689

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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/631,613

Applicant(s)

HOGREFE ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 12 July 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment to advisory action. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 69, 70, 72, 74.

Claim(s) withdrawn from consideration: _____

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☒ Other: Interview Summary enclosed 8/10/05
Cynthia B. Wilder, Ph.D.
Examiner
Art Unit: 1637

500

ATTACHMENT TO ADVISORY ACTION

1. Applicant's amendment filed on July 12, 2005 is acknowledged, but will not be entered because it does not place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Specifically, the claims as amended do not satisfy the issues raised under 35 U.S.C. 112 first paragraph as lacking enablement. While the Examiner acknowledges Applicant's arguments that the specification in Example 15, section 2, demonstrates enhancement of nucleic acid polymerase reactions composition for several different polymerases other than Pfu DNA polymerase, it is noted that the specification only demonstrates enhancement of the nucleic acid polymerases selected from the *pyrococcus* species and Vent DNA polymerase but does not teach or demonstrate wherein any other polymerase besides those noted above are capable of being enhanced by the claimed method and PEF composition. There is no indication from the specification that any of the plethora of known nucleic acid polymerases are functional in the presence of the PEF composition. In fact, Applicant's specification at page 63 teaches testing for example, e.g., Taq DNA polymerase, which is isolated originally from the thermophilic eubacteria *Thermus aquaticus*. The specification teaches that it was concluded that the PEF composition may not enhance the yield of PCR products generated with Taq DNA polymerase. Hence, Applicant's specification clearly shows that the claimed method is not capable of enhancing the activity of any and all nucleic acid polymerases known in the art. In response to Applicant's arguments that the quantity of experimentation left to one of skill in the art is low, it is noted that contrary to applicant's arguments, one cannot predict the outcome of a nucleic acid polymerase reaction in the presence of an enhancing factor, such as PEF, and any nucleic acid polymerase without further undue

Art Unit: 1637

experimentation to determine the effects of the enhancing factor on the desired nucleic acid polymerase. Due to the lack of guidance and working examples in the specification, one cannot predict that a desired polymerase reaction will be enhanced using the claimed method as described. Thus it is concluded that Applicant's specification is not enabled for a method of enhancing any nucleic acid polymerases or a method for controlling the activity of any polymerase in a polymerase that is commensurate fully in scope. Further undue experimentation is deemed necessary.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1637

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/17/05